

REMARKS

Claims 1 - 21 are pending in this application. The allowance of claims 15 - 17 is gratefully acknowledged. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1, 2, 4 - 6, 9, 11, 18 and 20 stand rejected under 35 U.S.C. § 103 as unpatentable over Storz-Irion (PCT Publication No. WO 01/80746) in view of Thompson (U.S. Patent No. 5,662,654). The Examiner stated, in support of the rejection, that Storz-Irion shows a device as claimed except for the anchoring elements which are quite different in Storz-Irion as compared to those recited in the claims. The Examiner further stated that Thompson shows anchoring members as claimed and that it would have been obvious to have substituted the anchoring elements of Thompson for those of Storz-Irion to arrive at the claimed invention.

Claim 1 recites a device for suturing an opening in an internal organ of a patient comprising "a first catheter for insertion to an opening to be sealed through a working channel of an endoscope" and "a plurality of anchoring members received within [a] first catheter, each of the anchoring members including a shaft extending from *a tissue penetrating distal tip* to a suture receiving proximal end and a gripping arm moveable between an insertion configuration in which the gripping arm is folded against the shaft and a gripping configuration in which the gripping member extends away from the shaft" and "a driving member extending through the first catheter to a proximal end thereof, wherein advancing the driving member distally into the first catheter advances the anchoring members distally through the first catheter to drive a distal-most one of the anchoring members out of the first catheter to anchor in tissue" in combination with "*a length of suture extending between the suture receiving proximal ends of the anchor members.*"

Similarly, claim 18 recites a device for suturing tissue within a body of a patient comprising "a plurality of anchoring members, each extending from "a tissue penetrating distal

tip to a suture receiving proximal end" in combination with *a length of suture extending between the suture receiving proximal ends of the anchor members.*"

As the Examiner has noted, the circular securing elements 6 in Storz-Irion do not resemble the anchor members of the Applicant's invention. (See 2/9/05 Office Action, ¶ 1). The securing elements 6 in Storz-Irion lack several elements of the Applicant's claimed anchor members, including "suture receiving proximal ends." Further, as the Examiner has noted, the securing elements 6 in Storz-Irion fix-position the thread 5. (*Id.*). The fix-positioning occurs when a securing element 6 is forced into an opening in tissue in which thread 5 has previously been deposited, thereby securing the thread in the opening. (See Storz-Irion, Fig. 2). This fix positioning is inconsistent with the threading of "a length of suture...between the suture receiving proximal ends of the anchor members" as recited in claim 1. That is, if the suture is not pinned between the distal end of the Storz-Irion securing element and the tissue, the thread will not be fixed in place and the securing elements will not operate as desired.

The Examiner further states that Fig. 3 of Storz-Irion shows a suture extending through both distal and proximal ends of each securing element 6. (See 2/9/05 Office Action, ¶ 19). As seen in Fig. 3 of Storz-Irion, the thread 5 passes loosely through a bore in each securing element 6. The description of Fig. 3 states that "[t]he securing elements 6 can [be]...loose with the thread 5 (FIG. 3)..." (See Storz-Irion, ¶ [0029]). Thus, in Fig. 3, the securing elements 6 are not linked together in any manner, and there is no showing or suggestion that the thread 5 is passed through a suture receiving proximal end of an anchor member of the Storz-Irion device in Fig. 3 or in any other part of this patent. The arrangement of securing elements 6 in Fig. 3 presents a problem similar to that described in regard to the arrangement disclosed in Fig. 2. That is, if the securing element 6 is not deposited deep enough in the tissue so that at least one hole of the bore (i.e., the distal end of the securing element 6) is pinned against tissue, the thread 5 will not be fixed in place, and the securing elements 6 will not operate as desired. Furthermore, because the securing elements 6 do not include "suture receiving proximal ends," a thread 5 cannot extend therebetween. As seen in Figs. 3 and 4 of Storz-Irion, the thread 5 attaches a distal end of the

securing element 6 to a proximal end of an adjacent securing element. This is further shown in Fig. 6 of Storz-Irion, where the thread 5 attaches the proximal end of a fully deployed securing element 6 to the distal end of a non-deployed securing element 6. Thus, it is respectfully submitted that Storz-Irion does not disclose or suggest "a length of suture extending between the suture receiving proximal ends of the anchoring members," as recited in claim 1.

The Examiner cites Thompson to cure these deficiencies of Storz-Irion. However, it is respectfully submitted that Thompson is insufficient to cure these deficiencies as Thompson discloses bone anchors which are for use only individually (i.e., with only one bone anchor per length of suture). That is, Thompson states that once a single bone anchor 9 has been deposited into a selected portion of bone 12, a length of suture 10 attached thereto is tied around a piece of tissue to lift the tissue to a desired position relative to the bone 12. (See Thompson, col. 15, lines 23-34; Fig. 2). Thompson neither shows nor suggests any other use for its bone anchors and clearly neither shows nor suggests connecting multiple bone anchors via a length of suture coupled to proximal ends thereof.

Furthermore, it is respectfully submitted that the bone anchor of Thompson is inserted into a preformed bore 13 and never penetrates any tissue. (See Thompson, col. 7, lines 31-32). Thus, it is respectfully submitted that Thompson also fails to show or suggest an anchoring member comprising "a tissue penetrating distal tip," as recited in claim 1. The Examiner has stated that Thompson's bone anchors are capable of piercing both bone and flesh to anchor in bone tissue. (See 2/9/05 Office Action, ¶ 20). Initially, it should be noted that, at no point, does Thompson ever disclose or suggest that the bone anchors 9 may be used to penetrate tissue. In fact, Thompson states that the bone anchor 9 is received (i.e., embedded) in a bore previously created in a pubic bone utilizing a drill tamper tool. (See Thompson, col. 12, lines 64-67). Furthermore, Thompson specifies that it is preferable that a boring tip 21 on the drill tamper tool to be blunt so as not to penetrate soft tissue or organs during creation of the bore which receives the bone anchor 9. (Id. at col. 11, lines 30-40; Figs. 5-7). Thus, neither the drill tamper tool nor the bone anchor 9 includes any structure for penetrating tissue.

Additionally, Thompson does not disclose or suggest that the bone anchor 9 may be used for "suturing an opening in an internal organ of a patient," as recited in claim 1. In fact, the main thrust of Thompson is a method of treating stress urinary incontinence by lifting a urethra 2 from a depressed position using the suture 10 tied around the single bone anchor 9, after it has been affixed to the pubic bone 12. (*Id.* at col. 7, lines 24-30). The Examiner states that both Storz-Irion and Thompson are intended for the application of fasteners with suture to bone and other kinds of tissue. (*See* 2/9/05 Office Action, ¶ 17). As stated above, Thompson does not disclose or suggest applying the bone anchor 9 to anything other than bone. Furthermore, Thompson does not disclose that the bone anchor 9 may be used in any manner for closing openings, much less to "suture an opening in an internal organ," as recited in claim 1.

The Examiner further states that the language of claims 1 and 18 does not exclude intended uses other than endoscopically suturing the inside of a stomach. (*See* 2/9/05 Office Action, ¶ 18). Initially, it should be noted that claims 1 and 18 are not in any manner limited to, as the Examiner has suggested, endoscopically suturing the inside of the stomach. Specifically, claim 1 recites "a device for suturing an opening in an internal organ of a patient," and claim 18 recites "a device for suturing tissue within a body of a patient." Neither of these claims include any language which would limit their scope to endoscopically suturing the inside of the stomach.

Thus, it is respectfully submitted that neither Storz-Irion or Thompson either shows or suggests a device for suturing an opening in an internal organ of a patient comprising "a plurality of anchoring members received within [a] first catheter, each of the anchoring members including a shaft extending from *a tissue penetrating distal tip to a suture receiving proximal end*" and "a driving member extending through the first catheter to a proximal end thereof, wherein advancing the driving member distally into the first catheter advances the anchoring members distally through the first catheter to drive a distal-most one of the anchoring members out of the first catheter to anchor in tissue" in combination with "*a length of suture extending between the suture receiving proximal ends of the anchor members,*" as recited in claim 1. Similarly, it is respectfully submitted that neither Storz-Irion or Thompson either shows or

suggests a device for suturing tissue within a body of a patient comprising "a plurality of anchoring members, each extending from "a tissue penetrating distal tip to a suture receiving proximal end" in combination with *a length of suture extending between the suture receiving proximal ends of the anchor members,*" as recited in claim 18.

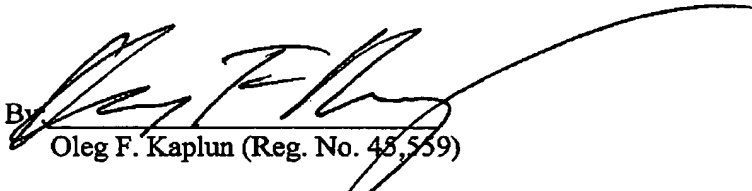
Therefore, at least for the above-stated reasons, it is respectfully submitted that Thompson is insufficient to cure the deficiencies of Storz-Irion, and claims 1 and 18 are allowable over Storz-Irion and Thompson, taken alone or in combination. Because claims 2, 4 - 6, 9, 11 and 19 - 21 depend from and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claims 3, 7, 8, 10, 12 - 14, 19 and 21 stand objected to as dependent upon rejected base claims. In view of the above remarks concerning the allowability of claims 1 and 18 from which these claims depend, it is respectfully submitted that these claims are in condition for allowance.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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